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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,648	02/05/2001	Toshiaki Takezawa	202785US0X	3290
22850	7590	11/04/2003	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/775,648

Applicant(s)

TAKEZAWA ET AL.

Examiner

Maria B Marvich, PhD

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED 30 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: 6, 7, 9, 22, 23, 27-29 and 31.

Claim(s) rejected: 1-5, 8, 10-21, 24-26 and 30.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: \_\_\_\_\_

Continuation of 2. NOTE: Claim 2 has been amended to recite that the cell incorporated type three-dimensionally reconstructed tissue is tissue organ engineered. The designation that the tissue is tissue/organ engineered changes the scope of the claimed invention and necessitates further search and consideration.

Applicants have not amended the claims to overcome the rejections of claims 1-5, 8, 10-21, 24-26 and 30 under 35 USC 102(e) and 35 USC 112, second paragraph. Claims 2 and 11-21 have been rejected under 35 USC 112, second paragraph as the claims are vague and indefinite in that the metes and bounds of the term "derived from" is unclear. It is unclear the nature and number of steps required in order to obtain biological material "derived from the same or a different animal". As a result, it is unclear the structural/functional characteristics of such a derivative. Applicants have not amended the claims to more clearly recite the invention. Claims 1-5, 8, 10, 11, 13, 17-19, 24-26 and 30 have been rejected as being anticipated by Spaulding et al. Applicants have not amended the claims to overcome the rejections under 35 USC 102(e).

Continuation of 5. does NOT place the application in condition for allowance because: the applicant's arguments are moot in view of the non-entry of the after final amendment.

Applicants traverse the rejection of Claims 1-5, 8, 10-11, 13, 17-19, 24-26 and 30 under 35 USC 102(e) as being anticipated by Spaulding et al on page 15-17 of the amendment filed 9/30/03. Applicants argue that Spaulding et al do not anticipate "a cell incorporated type three-dimensionally reconstructed tissue" as a means for inducing adhesion and three-dimensional growth of a fertilized ovum as defined in the instant invention. In the carrier of the instant invention, the "cells are beforehand incorporated in a culture carrier" that contains an extracellular matrix component and/or mesh network. Applicants argue that Spaulding et al teach materials that do not allow cells to be incorporated into the culture carrier.

Applicants arguments filed 9/30/03 have been considered but are not persuasive. Applicants recite a carrier that is comprised of a cell incorporated type three-dimensionally reconstructed tissue as a means for inducing adhesion and three-dimensional growth. The term "a cell incorporated type three-dimensionally reconstructed tissue" does not have an art defined meaning or description. In Paper No 6, page 9, filed April 14, 2003, this term is defined as a scaffold for growing three-dimensional tissue derived from fertilized ovum. Given this definition, the invention of Spaulding et al does anticipate the instant invention. Spaulding et al teach a carrier for developing embryos in which a fertilized egg adheres (is implanted) and matures. The carrier is specifically designed for three-dimensional tissue growth. The carrier is endometrial tissue used in conjunction with a roller bottle that is made of material suitable for cell and tissue culture. Applicants have not indicated that materials suitable for tissue culture can not be included in the carrier. In fact, in figure 1 of the instant specification, a tissue culture plate is used in conjunction with gauze as a co-culturing carrier. Furthermore, Spaulding et al contemplate the use of nylon in the roller bottle (column 7, line 29). Applicants, in paragraph 0058, list nylon as a preferred mesh network. According to the invention, the mesh network is a component of the carrier. Absent evidence to the contrary, the invention of Spaulding et al meet the limitations of the instant invention.

  
GERALD B. LEFFERS  
PRIMARY EXAMINER